



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

CivaTech Oncology, Inc.
% Mr. Blix Winston
Submission Correspondent
Tammnet, Inc.
2600 Mullinix Mill Road
MT AIRY MD 21771

August 29, 2014

Re: K140490
Trade/Device Name: CivaSheet PD-103
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: KXX
Dated: August 21, 2014
Received: August 22, 2014

Dear Mr. Winston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140490

Device Name

CivaSheet

Indications for Use (Describe)

CivaSheet is indicated for use as a permanent interstitial brachytherapy source for the treatment of selected localized tumors. The device may be used either as the primary treatment or for treatment of residual disease after excision of the primary tumor. CivaSheet may be indicated for use concurrently with or sequentially with other treatment modalities, such as external beam radiation therapy or chemotherapy.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Attachment 8: 510(k) Summary K140490

1. 510(k) Submitter:

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2. Submission Correspondent:

Blix Winston
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2600 Mullinix Mill Road
Mt. Airy, MD 21771
Phone: 301-607-9185
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3. Date Prepared: February 26, 2014

4. Name of Device:	CivaSheet
Common Name:	Radionuclide Brachytherapy Source
Classification Name:	Brachytherapy Radionuclide
	Regulation 21 CFR 892.5730, Product Code
	KXX

5. Identification of device(s) to which the submitted device claims equivalence:

- CivaString by CivaTech Oncology Inc., K082159

6. Device Description:

The CivaSheet is a planar brachytherapy device designed to be implanted in the body to treat selected localized tumors. The CivaSheet utilizes biocompatible materials to encapsulate Pd-103, a radionuclide with a long history in radiotherapy. CivaSheet will be offered in two configurations: a shielded unidirectional version, and an unshielded version. Both versions are intended as permanent implants and are partially bio-absorbable.

7. Intended Use of the Device:

CivaSheet is intended for medical purposes to be placed into a body cavity or tissue as a source of nuclear radiation for therapy.

8. Indications for Use

CivaSheet is indicated for use as a permanent interstitial brachytherapy source for the treatment of selected localized tumors. The device may be used either as the primary treatment or for treatment of residual disease after excision of the primary tumor. CivaSheet may be indicated for use concurrently with or sequentially with other treatment modalities, such as external beam radiation therapy or chemotherapy.

9. Characteristics of the device in comparison to those of the predicate device

When compared with the Intended Use and Indications for Use of the predicate, the Intended Use and Indications for Use do not change.

The design of the predicate and CivaSheet is a sealed source from which a therapeutic dosage of radioactive energy is delivered. The predicate device uses a sealed source in a linear configuration. CivaSheet uses a sealed source in a sheet configuration.

The energy emitted from CivaSheet is exactly the same as current Pd 103 sources: 20-23 keV x-rays.

10. Safety and Performance:

The difference between the CivaSheet and the above mentioned predicate devices does not raise any new questions regarding the safety and effectiveness of the device. The device, as designed, is as safe and effective as its predicate device.

11. Conclusion

Based on the design, material, function and intended use discussed herein, CivaTech Oncology, Inc. believes the CivaSheet is substantially equivalent to predicate device currently marketed under the Federal Food, Drug and Cosmetic Act.